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APPLICATION NO. 116,000,000	FILING DATE 05/24/00	FIRST NAMED INVENTOR WITMER	ATTORNEY DOCKET NO. 9616.DIP3.01
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EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1631

12

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/132,156

Applicant(s)

Wittmer et al.

Examiner

Ardin Marschel

Group Art Unit

1631



X Responsive to communication(s) filed on Mar 1, 2000

X This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

X Claim(s) 30-45, 57, and 58 is/are pending in the application

~~or none~~ Claim(s) 1-29 and 46-56 have been canceled. ~~are withdrawn and prosecution~~

Claim(s) _____ is/are allowed.

X Claim(s) 30-45, 57, and 58 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, ~~09/132,156~~ (3 sheets)

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 3/1/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 30-45 and 57 are rejected, as discussed below, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for amplification reactions performed in a capillary vessel, does not reasonably provide enablement for other or any reaction vessels or sample holding structure. This rejection is reiterated and maintained from the previous office action, mailed 8/19/99, and as necessitated by amendment regarding additional claims listed above due to the broadening amending, for example, in claim 30, line 5. Applicants have alleged in arguments that a variety of non-capillary vessels are usable and enabled in achieving the rapid cycle times of the instant invention. This is countered by the factual basis described for this rejection as reiterated below from the previous office action, mailed 8/19/99. A factual basis for a rejection is deemed to prevail over allegations.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. It is firstly noted that instant claims 30-45 and 57 lack any capillary reaction vessel limitation. It has been discussed in Wittmer et al.(1991) that temperature cyclers are not available in the biochemical community to perform rapid cycling as summarized in the first full paragraph on page 82, third column. The instant specification also has not achieved the rapid step times as instantly claimed without also utilizing capillary reaction vessels. More discussion of the slowness of temperature changes is given in said Wittmer et al. reference on pages 78-80 in the DISCUSSION section, first 5 paragraphs, wherein heat block etc. temperature control devices are not capable of changing temperature as rapidly as required in the instant claims. The need for such capillary reaction vessels is discussed in Swerdlow et al.(1993) in the bridging paragraph between pages 512 and 513. In summary, only the practice of capillary reaction vessel usage is instantly enabled so as to achieve the instantly claimed rapidity of temperature step changes. No guidance has been found so as to make such rapid temperature changes without the usage of said capillary vessels.

PRIORITY FOR THE INSTANTLY CLAIMED INVENTION:

Priority is claimed by applicants and argued as being

supported in all prior parent applications via Example 1 and Figures 6 and 7 of the instant application. Upon consideration, these disclosures do not support a priority date for the instant claims that include prior parent documents. Priority is granted if all features of the invention upon which priority is requested have support in the desired priority documents. Regarding instant claim 30, for example, part (a) is directed to a "sample holding structure" which does not have written basis for such a generic structure in either Example 1 or Figures 6 or 7, nor does the step (g) times of "approximately 10 to 90 seconds". Nowhere in the claimed supporting disclosures is there written support for the phrase "at least 15°C higher" in step (b) of instant claim 30. Also, the Example 1 thermal cycling method utilizes air heat and cooling which is a vastly more limited thermal cycling means than instant claim 30 which is generic in this regard. Similarly, instant claim 35 lacks written support for the phrases "at least 15°C" and "approximately 10 to 60 seconds" as well as also not being limited to air temperature control. Rather claim 36 is broader in utilizing a "heated fluid" in line 5. In summary, if applicants can point to written basis for the instant claims that support priority, this will be reviewed again, but the present priority claim is not granted to these parent application disclosures.

The following is a quotation of the appropriate paragraphs

of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 31, 33, 35, 37, 39-41, 43, 45, 57, and 58 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Wittmer et al.(1991).

This rejection is reiterated and maintained from the previous office action, mailed 8/19/99, and as necessitated by amendment due to the non-granting of priority as discussed above as the only argument against this rejection.

Wittmer et al.(1991) on pages 76-78 teaches various capillary vessel amplification procedures with rapid cycle times. In Figure 1, for example, 30 repetitive cycles are completed in 14-16 minutes which computes to 0.47 - 0.53 minutes or 28 - 32 seconds per cycle. Within each cycle are the temperature raising, holding, lowering steps of the instant claims including first and second temperatures as instantly claimed with differences greater than 15°C as describes on page 77, middle column, first full paragraph. The step completion clearly is 60 seconds or less as also disclosed on said page 77, middle column, first full paragraph. A 10 ul sample definition in the capillary vessel is disclosed on page 76, third column, last sentence, as

also required in instant claim 31. The three temperature cycle profile of instant claim 33 is given in Figure 7 on page 80 of the reference. The conditions of the capillary reaction method in the reference appears to be the same as the instant invention wherein a 10 ul sample maintains the temperature homogeneity as required for instant claim 35. See the below cited legal decisions wherein the prior art appears to disclose an instant invention without analyzing some characteristic that is expected to be present if the same materials are practiced. The "less than 1 seconds" annealing temperature limitation of instant claim 37 is given in the reference on page 77, middle column, first full paragraph. The rate limitation of instant claim 39 is given in the reference on page 77, middle paragraph, wherein $92-56 = 36^{\circ}\text{C}$ in 9 seconds which equals 4°C per second. The denaturation time limitations of claims 41 and 43 is also given in said page 77 disclosure.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first

full paragraph).

Claims 50-48, 57, and 58 are rejected under 35 U.S.C. § 102 b as being clearly anticipated by Swerdlow et al. (1993).

This rejection is reiterated and maintained from the previous office action, mailed 8/19/99, and as necessitated by amendment due to the non-granting of priority as discussed above as the only argument against this rejection.

Swerdlow et al. discloses the same PCR amplification therein as in the above reference but additionally discloses the 0 second programmed denaturation and annealing holding times on page 514, third column, as given in the instant claims directed to such times being less than 1 second.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 30, 31, 33, 35, 37, 39-41, 43, 45, 57, and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haff et al. (P/N 5,827,480).

This rejection is reiterated and maintained from the previous office action, mailed 8/19/99, and as necessitated by amendment due to the non-granting of priority as discussed above as the only argument against this rejection.

Haff et al. describes PCR methodology utilizing capillary tubes in column 7, first column, first paragraph. The second paragraph of this same column cites first and second temperatures that are greater than 15 degrees apart with holding or residence times of 1-300 seconds. The lower end of these holding times clearly gives species within the instant claim step times. 10 ul capillary volumes and thermostable polymerase practice are defined in column 12, lines 37-48, as well as short holding times for denaturation etc. as instantly claimed. Taken as a whole Haff et al. discloses a variety of temperatures, holding times, capillary vessels, etc. as given in the instant claims and Haff et al. overall is directed to utilizing these options as desired in amplification reactions.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice

the instant invention because Haff et al. suggests and motivates methodology species of the instant claims as summarized above.

The disclosure is objected to because of the following informalities:

Applicants have submitted a PROGRAMMING CODE APPENDIX which has not been amended into the instant specification because of confusion as to where to enter it. Applicants are requested to clarify what is desired as to this appendix. Where it is, or is not, to be amended into the specification should be cleared up.

Appropriate correction is required.

Two citations on the enclosed PTO Form 1449 have been lined through due to a lack of a date of publication.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CMI Fax Center number is either (703) 308-4242 or (703) 308-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 21, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER